

## REMARKS

### **Introduction**

Receipt of a non-final office action dated July 28, 2006 is acknowledged. In the action, the claims are rejected allegedly for indefiniteness, failing to meet the written description requirements, and obviousness reasons.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **Status of the Claims**

In this response, claims 1 and 3 are amended. Support for the claim amendments can be found on page 11, lines 3-23. Upon entry of this amendment, claims 1-4, 6-9, 13, and 15-16 will be under examination.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

### **Rejection Under 35 U.S.C. §112, 2<sup>nd</sup> Paragraph**

Claims 1-4, 6-9, 13 and 15-16 are rejected for as allegedly indefinite. In particular, the Office indicated that the phrase "and another peptide or polypeptide" is vague. In the interest of expediting prosecution, and without acquiescing to the Office's rejection, Applicants amended the claims to recite that the fusion protein comprises the protein described in the above (a) or (b), and a peptide selected from a group consisting of FLAG, 6 x His comprising 6 histidine residues, 10 x His, influenza hemagglutinin, fragments of human c-myc, fragments of VSV-GP, fragments of p18HIV, T7-tag, HSV-tag, E-tag, fragments of SV40T antigen, lcktag, fragments of  $\alpha$ -tubulin, B-tag, and fragments of Protein C, or a polypeptide selected from a group consisting of glutathione S-transferase, HA, the constant

regions of immunoglobulin,  $\beta$ -galactosidase, and maltose-binding protein. Support for this amendment can be found on page 11, lines 3 to 23 of the English specification.

Applicants trust that this amendment addresses the Office's concerns.

**Rejection Under 35 U.S.C. §103**

Claims 1, 3, 7-9 and 13 are rejected as allegedly obvious over Goto *et al.* (Blood, 84(6)), in view of Hirano *et al.* (US Patent No. 5,914,252), and claims 2, 4, 6 and 15-16 are rejected over Goto, in view of Hirano and Kang *et al.* (US Patent No. 5,656,448). Applicants respectfully traverse this ground for rejection.

The Goto reference describes immuno-precipitation of an anti-HM1.24 antibody, and the Hirano reference describes an amino acid sequence of Bst-2 molecule recognized by an anti-HM1.24 antibody. These references, however, separately or in combination, do not suggest the present invention.

Specifically, the present invention is characterized by the use of "soluble HM1.24 antigen protein", as supported by Examples 8, 17, 19 and 20. Neither the Goto *et al.* reference nor the Hirano *et al.* reference suggests the presence of the soluble HM1.24 antigen protein. Please note that the soluble HM1.24 antigen protein is clearly defined by its amino acid sequence by referring to SEQ ID NO: 1.

Natively, the HM1.24 antigen protein is insoluble. The HM1.24 can be made soluble by truncating a part of the C-terminal region. Neither the Goto *et al.* reference nor the Hirano *et al.* reference suggests that the HM1.24 antigen protein can be made soluble by truncating its C-terminal region.

Furthermore, the deficiencies in the combination of Goto and Hirano are not taught in Kang.

Therefore, Applicants assert that the pending claims are not obvious in view of Goto and Hirano, or the combination of Goto, Hirano and Kang, and respectfully request that this rejection be withdrawn.

**Rejection Under 35 U.S.C. §112, 1<sup>st</sup> Paragraph**

Claims 1-4, 6-9, 13 and 15-16 are rejected for allegedly failing to comply with the written description requirement. In particular, the Office stated that there is no support for the limitation “lacking 27 or less amino acids fro [sic] the N-terminal” but that “[t]he examiner found support for and [sic] N-terminal deletion of the transmembrane domain, which could be 27 amino acids.” Office action at 6.

In the interest of expediting prosecution, and without acquiescing to the Office’s rejection, Applicants amended claims 1 and 3 to recite “lacking 27 amino acids.”

### CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

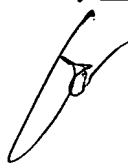
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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